

**REMARKS**

**I. Status of the claims**

Claims 6-9 are pending in this application. No claim is being amended in this response.

**II. Rejections withdrawn**

Applicants acknowledge the Office's withdrawal of the rejection under 35 U.S.C. § 103(a) over *Achstetter* in view of *Schmid*.

**III. Rejections under 35 U.S.C. § 112, first paragraph**

The Office rejected claims 6-9 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Office argues that "[t]he added limitation that the *E. coli* bacteria used in the process are not *E. coli* secretor mutants is considered new matter."

The Office argues that "[t]he Specification as a whole does not teach that the type of *E. coli* strain is important or that non-secretor mutants should be used." Office Action at p. 4. The Office further argues that "since the Specification as a whole teaches that any *E. coli* strain could be used and is not important to the invention, the negative limitation that the *E. coli* bacteria are not *E. coli* secretor mutants is considered new matter." *Id.* The Office concludes that "[f]or the reasons stated above, it does not appear that, at the time of filing, Applicant contemplated the exclusion of *E. coli* secretor mutants from the process of the invention." *Id.* Applicants respectfully traverse this rejection.

Respectfully, the Office has not applied the proper standard to determine whether Applicants' amendment complies with the written description requirement of

35 U.S.C. § 112, first paragraph. The standard is not whether the Specification as a whole teaches that the type of *E. coli* strain is **important** or that non-secretor mutants **should** be used as argued by the Office. The standard is “whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicants was in possession of the invention as now claimed,” i.e., wherein the *E. coli* bacteria are not *E. coli* secretor mutants. M.P.E.P. § 2163.02.

At the time of filing, Applicants were in possession of methods for selecting a signal peptide for secretory expression of a desired hirudin or hirudin derivative protein in *E. coli*, wherein the *E. coli* bacteria are not *E. coli* secretor mutants. For example, the specification discloses that experiments were carried out with cells of the *E. Coli* strain Mc1061, or with secretor mutants. Specification at p. 9, lines 1-3. Because the *E. Coli* strain Mc1061 is not an *E. coli* secretor mutant, Applicants were in possession of the methods instantly claimed.

Furthermore, the propriety of the claim amendments rejected by the Office is supported by the M.P.E.P. and case law. For example, it has been recognized that inventors may claim less than the full scope of their disclosure and that “[i]f alternative elements are positively recited in the specification, they may be explicitly excluded in the claims.” M.P.E.P. § 2173.05(i) (citing *In re Johnson*, 558 F.2d 1008,1019 194 U.S.P.Q. 187, 196 (C.C.P.A. 1977)). In this case, Applicants describe experiments where secretor mutants were used and now are carving out subject matter drawn to those secretor mutants from the claims. There is no requirement that the specification indicate that such an exclusion is important as is being required by the Examiner. For

at least the foregoing reasons the claim amendments at issue are fully supported by the specification and Applicants respectfully request that this rejection be withdrawn.

Finally, Applicants have the statutory right to select, from what is disclosed in the specification, the subject matter they regard as their invention. U.S.C. 35 § 112, ¶ 2. And, the courts have specifically recognized that "[s]ince the patent law provides for the amendment during prosecution of claims, ...the second paragraph of 35 U.S.C. § 112 does not prohibit the applicant from changing what he 'regards as his invention' (i.e. the subject matter on which he seeks patent protection) during the pendency of his application." *In re Saunders*, 444 F.2d 599, 607, 170 U.S.P.Q. 213, 220.

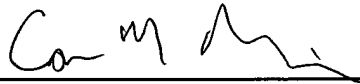
#### IV. Conclusions

In view of the foregoing remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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